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# LABORATORY SCIENTISTS AND LABORATORY TECHNICIANS: POLICY OPTIONS

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## AUTHORITY

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Delegate John M. O'Bannon introduced House Bill No. 601 during the 2010 Session of the Virginia General Assembly. The bill proposed registration of medical laboratory scientists and medical laboratory technicians. By virtue of its statutory authority in §54.1-2510 of the Code of Virginia to advise the Governor, the General Assembly, and the Department Director on matters related to the regulation and level of regulation of health care occupations and professions, the Board of Health Professions is reviewing the need for regulation of laboratory scientists and technicians pursuant to the request from Delegate John M. O'Bannon.

The review was initially undertaken in summer of 2010 by an independent contractor, and the Board of Health Professions' Regulatory Research Committee (RRC) held a public hearing on July 16, 2010. The contractor submitted a document entitled *Study of the Need to Regulate Medical Laboratory Scientists and Laboratory Technicians* in September of 2010. At its September 29, 2010 meeting, the RRC recommended that some regulation of medical laboratory scientists and technicians was warranted. However, action was tabled pending further research on the proper form of regulation. Completion of the study was undertaken by Board of Health Professions staff.

On April 14, 2011, staff received documents from the Centers for Medicare & Medicaid Services (CMS) pertaining to a Freedom of Information Act (FOIA) request submitted by the independent contractor for documents related to complaints and deficiency citations in Virginia's clinical laboratories. The RRC reviewed these documents at its June 20, 2011 meeting and requested staff to prepare a description of policy options. Since the Board has experienced turnover, we have also included a summary of staff findings in this document.

## SUMMARY OF FINDINGS

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### **1. Laboratory tests are an essential part of modern medical practice, and their quality directly influences patient health.**

Health and laboratory workers perform over 10 billion laboratory tests every year. Up to 80 percent of medical diagnoses are based on laboratory test results. Laboratory tests are often essential for developing treatment plans, including drug regimens and transfusions. Inaccurate laboratory results, or delays in providing results, can result in significant harm to patients, including death.

**2. Clinical laboratories and tests are changing rapidly due to technological advances.** Technological change is affecting clinical laboratories and tests in two ways. First, new tests are being developed at the vanguard of medical practice in areas such as genetics and molecular medicine. Performing and understanding these tests often requires new skills and updated education in these areas. Meanwhile, technological advances are making existing tests easier and more routine to perform. Tests which previously required skilled professional judgment and expensive laboratory equipment are now provided at the point of care, in nursing homes, ambulances, pharmacies or in patient's homes. They are performed by nurses, pharmacy technicians, family caregivers or patients themselves. Most labs are not centralized independent or hospital labs, but are point of care labs. (See Table, next page).

### 3. Clinical Laboratory Workers fall into three generalist and various specialist roles.

#### Generalist Roles

- A. Medical Laboratory Scientists**—Perform laboratory tests on tissues and fluids. Scientists perform the most complex tests, develop procedures, interpret test results and maintain quality control processes, including responsibility for automated equipment testing processes.

*Training: Bachelor's in a life science or a combination of training and experience.*

- B. Medical Laboratory Technicians**—Perform laboratory tests on tissues and fluids. Technicians perform less complex tests, prepare specimens for analysis and perform manual tests with detailed instructions. Technicians usually work under the supervision of scientists or otherwise qualified laboratory managers.

*Training: Post-Secondary Certificate or Associate Degree, or a combination of training and experience.*

- C. Phlebotomists**—Collect and process blood and other laboratory samples, usually under the supervision of a laboratory technician.

*Training: On the job training or training certificate.*

#### Examples of Specialist Roles

- A. Cytotechnologists**—Prepare and analyze cell samples for abnormalities indicating disease. Generally, cytotechnologists analyze Pap smear tests and other tests for cancer.

*Training: Bachelor's degree in cytotechnology, or a post-graduate training certificate in cytotechnology*

- B. Histotechnologists**—Prepare thin tissue slices for examination under a microscope by a clinical pathologist.

*Training: Bachelor's degree with a science emphasis and advanced training or one year experience working with a pathologist.*

- C. Specialists in Blood Banking**—Specialists in blood center and transfusion services operations. Collect and process blood, analyze blood types and blood abnormalities, and provide transfusion therapy services.

*Training: Postgraduate certificate or master's degree*

Lab Type	# Certified in Virginia	# Waived	Percent Waived
AMBULANCE	16	14	88%
AMBULATORY SURGERY CENTER	72	62	86%
ANCILLARY TEST SITE	62	28	45%
ASSISTED LIVING FACILITY	4	3	75%
BLOOD BANKS	13	4	31%
COMMUNITY CLINIC	118	44	37%
COMPREHENSIVE OUTPATIENT REHAB	5	4	80%
END STAGE RENAL DISEASE DIALYSIS	127	126	99%
FEDERALLY QUALIFIED HEALTH CENTER	27	8	30%
HEALTH FAIR	17	17	100%
HMO	24	8	33%
HOME HEALTH AGENCY	209	207	99%
HOSPICE	51	48	94%
HOSPITAL	160	32	20%
INDEPENDENT	101	25	25%
INDUSTRIAL	42	40	95%
INSURANCE	2	2	100%
INTERMEDIATE CARE FACILITY	5	5	100%
MOBILE LAB	56	44	79%
OTHER	477	326	68%
OTHER PRACTITIONER	88	55	63%
PHARMACY	200	198	99%
PHYSICIAN OFFICE	2894	1449	50%
PRISON	4	4	100%
PUBLIC HEALTH LABORATORY	4	2	50%
RURAL HEALTH CARE CLINIC	23	9	39%
SCHOOL/STUDENT HEALTH SERVICE	64	42	66%
SKILLED NURSING/NURSING FACILITY	256	252	98%
TISSUE BANK/REPOSITORIES	2	0	0%
Total (January 2010)	5123	3058	60%

#### 4. The 1988 Federal Clinical Laboratory Improvement Amendments (CLIA) are the main regulatory apparatus ensuring the quality of clinical laboratory services.

The Centers for Medicare & Medicaid Services administers CLIA in conjunction with the Food and Drug Administration and the Centers for Disease Control and Prevention. All clinical laboratories (not just those receiving CMS reimbursement) are required to be certified through CLIA. CLIA's regulatory approach involves certifying clinical laboratories based on the type of laboratory tests performed. Certified laboratories must meet standards, including personnel standards, based on the complexity and the risk of harm of the tests performed, and their potential risk of harm. CLIA uses a combination of lab surveys, complaint investigations and proficiency testing to enforce standards. In Virginia, surveys and investigations are conducted by either the Virginia Department of Health, or a private accreditation agency "deemed" by CMS to have equivalent standards to CLIA. Proficiency testing is performed by private proficiency testing companies on behalf of CMS. Proficiency testing tests lab personnel individually as well as lab quality control measures in general. An outline of test categories, lab categories and their related standards and enforcement procedures appears below:

Test Type	Definition	CLIA Personnel Requirements
Waived	Low complexity and low risk of harm. These tests are often performed by providers at the point of care.	None
Moderate Complexity	Moderate Complexity and/or risk of harm	HS diploma and documented training
High Complexity	High complexity and/or risk of harm	Associate degree and completion of either: 1) accredited or approved clinical laboratory training program 2) three months laboratory training in specialty
Provider-Performed Microscopy Procedures (PPMP)	Moderate or High Complexity tests that must be performed at the point of care by a health care provider.	Physician, Dentist or Mid-level health care provider

CMS issues four types of certificates to labs (Figures from June, 2011):

Certificate	Definition	Requirements	National	In Virginia
Certificate of Waiver	Waived tests only	Must be certified. Subject to random, on-site inspections—about 2% of labs per year.	146,071 (66.7 %)	3,158 (60.8%)
Certificate of Compliance	Perform all tests Surveyed by State agency	Surveyed biennially. Proficiency testing quarterly.	19,319 (8.8%)	482 (8.7%)
Certificate of Accreditation	Perform all tests Surveyed by accrediting organization	Surveyed biennially. Proficiency testing quarterly.	15,787 (7.2%)	469 (9.0 %)
Certificate for Provider Performed Microscopy Procedures	Perform PPMP and waived tests only.	Subject to random, on-site inspections—about 2% of labs per year.	37,767 (17.2%)	1,086 (20.9%)
<b>Total</b>			<b>218,944</b>	<b>5,195</b>

#### 5. CLIA defines roles for clinical laboratory management.

CLIA identifies certain roles that must be filled within each laboratory. In the case of small labs performing a limited number of tests, these roles may be filled by one person. In larger labs, a qualified person may fill one or

more roles. CLIA qualifications are extremely detailed, and differ depending on the complexity of tests performed, the specialty area, and the individual tests. Requirements shown here are only general outlines.

**A. Laboratory Director:** The laboratory director is responsible for the overall operation and administration of the laboratory, including employment of competent personnel and quality control. Laboratory directors must be actively involved in operations and available to staff on an as needed basis. Laboratory directors may only oversee five non-waived labs. Tasks performed by other managing personnel are delegated by the laboratory director, and he is ultimately responsible for their activities. *Qualifications: A Board certified Clinical Pathologist, a physician with training or experience in clinical laboratory responsibilities, an experienced PhD in laboratory sciences, or a master's or bachelor's educated scientist with one or two years, respectively, of both laboratory work experience and laboratory supervisory experience.*

**B. Technical Consultant/Supervisor:** Technical consultants/supervisors are responsible for providing technical consultation for tests in each specialty or subspecialty performed by the lab. Consultants and supervisors have the same responsibilities; however technical supervisors are required for high complexity tests and have higher qualification requirements. Technical consultants/supervisors may be generalists, providing support for all lab tests, or specialists. However, they must have the required education, training or experience to provide technical expertise for tests in their area of responsibility. *Qualifications: Equivalent to laboratory director, but training and experiential requirements must be within requisite specialty areas.*

**C. Clinical Consultant:** Assists clients with interpretations of laboratory test results and their meaning for diagnosis, treatment plans and patient care. *Qualifications: The laboratory director or a physician.*

**D. Testing Personnel:** Perform tests. There must be a sufficient number of testing personnel to perform the volume of tests performed at the lab. *Qualifications: Generally, as noted in the chart in Section 4. Training and qualifications are specified according to the specific test(s) performed or to specialties and subspecialties. On-the-job, military or formal training at an educational institution are acceptable.*

## 6. CLIA-style regulation has advantages unique to clinical laboratories.

**A. Markets for laboratory tests are national:** Lab specimens are often sent across state borders for testing. State regulations will not affect tests sent across borders, or may prove onerous if they do so. State regulations that prove costly or burdensome may result in tests for Virginia's patients being sent out of state.

**B. Lab work lends itself to output/error testing:** Laboratories do not provide assessments, treatment plans, patient counseling or direct patient care. They provide analyses, the results of which may be objectively tested. Proficiency testing provides an objective test of competency.

**C. Technology is changing the nature of lab work:** More lab tests are becoming automated and less complex to perform. FDA classification of lab tests assimilate technological changes into regulations and personnel requirements. This allows tests that become routine to be performed at the point of care by health providers, while more complex or risky tests are subject to greater restrictions.

**D. Errors tend to be process-oriented:** Studies suggest that the majority of laboratory errors occur in the pre- and post-analytical phases of the testing process. Poor communication, breakdowns in specimen processing and other managerial/data issues influence these errors much more than the specialized skills associated with medical laboratory analyses. CLIA's process accounts for improvements in data processing,

quality control, communication and other management issues that improve lab quality as well as the quality of staff.

## 7. There are some notable criticisms of CLIA.

**A. Over 80% of labs are not subject to enforcement measures:** Waived labs and PMPP labs are not subject to surveys or proficiency testing. Additionally, a greater number and breadth of tests are being categorized as waived tests. In 2002, CMS initiated random on-site surveys of waived and PMPP labs after finding deficiencies in over 50 percent of these labs during a review. CMS is currently reviewing its process for regulating waived tests and laboratories.

**B. Sanctions are rare:** CLIA's goal is to improve quality in labs. Regulators view the survey process as educational as well as regulatory, and often allow labs to correct deficiencies before imposing sanctions unless there is a risk to patients or there are repeated deficiencies.

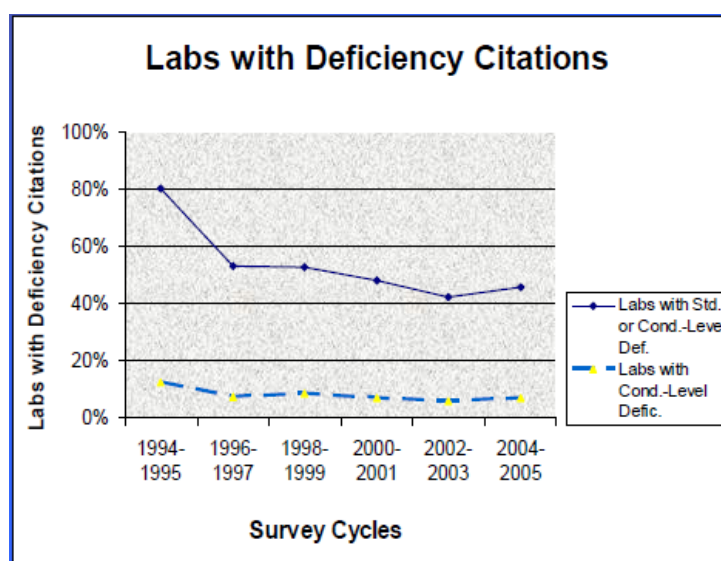
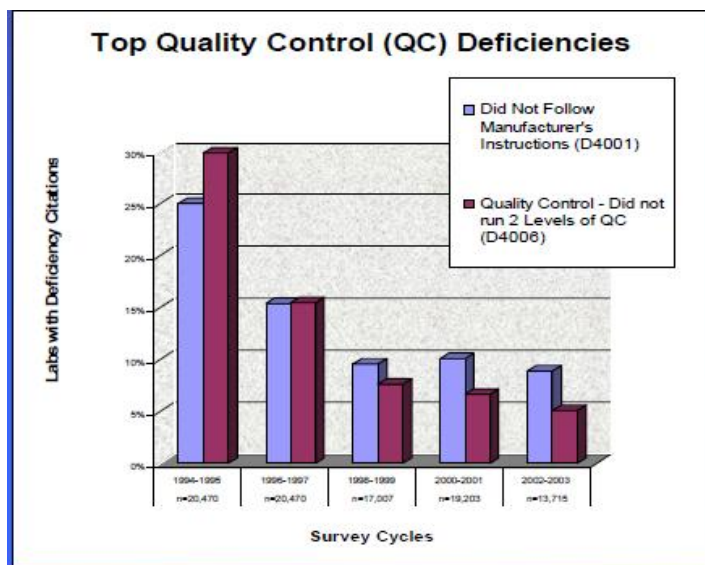
**C. Survey process is fragmented:** Survey and complaint investigations are conducted by agencies in each state and by six deemed accrediting organizations. Although all labs must meet CLIA or CLIA-equivalent standards, the ability of the survey organizations and their processes to identify deficiencies varies.

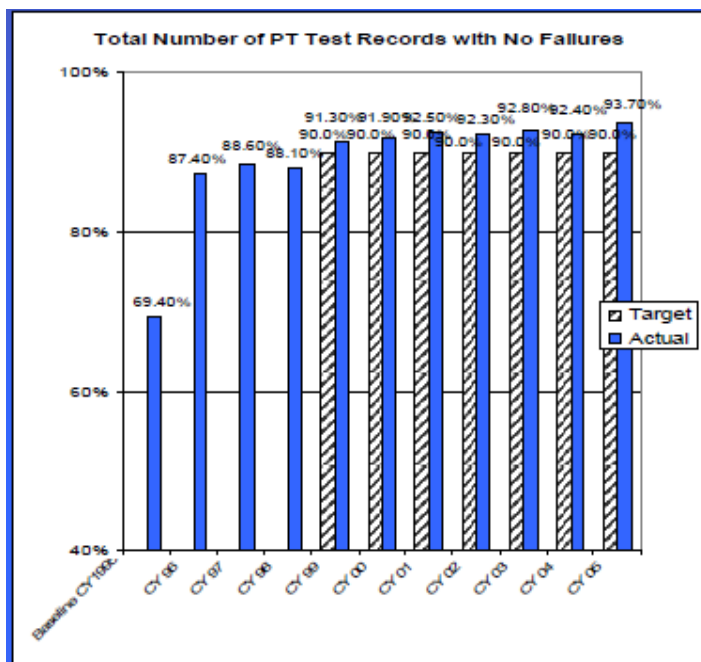
**D. It is unclear if CLIA has improved lab quality:** The lack of standardization of enforcement and data reporting makes it difficult to assess the efficacy of CLIA regulations at improving lab quality. Additionally, improvements in existing quality measures may be due to the growth of waived labs, which are not subject to CLIA surveys or proficiency tests, rather than real improvements in lab quality.

## 8. CMS measures show an increase in lab quality since CLIA was enacted.

CMS reports that on key measures, lab quality has improved since the introduction of CLIA. The following charts are from a presentation by Judith A. Yost, Director of CMS Laboratory Services, to the Clinical Laboratory Improvement Amendments Advisory Committee (CLIAC), a part of the CDC, in September 2006, available in the CLIAC minutes of the same date as Addendum E: <http://wwwn.cdc.gov/cliac/cliac0906.aspx>.

Deficiency citations for labs that did not have at least two levels of quality control and that did not follow manufacturer's instructions in lab procedures declined from about 20 percent and 30 percent, respectively, from the mid-90's to about five percent and eight percent in 2003. The proportion of non-waived labs with minor and major deficiencies has declined as well. Proficiency test pass rates for all tests increased from about 70 percent in 1996 to over 90 percent in 2006.





A 2006 GAO report outlined many of the criticisms of CLIA implementation. CMS undertook a series of changes as a result. CMS is currently examining changes in enforcement policies for Certificate of Waiver labs, including legislative changes to improve the level of oversight.<sup>1</sup>

#### 9. States must meet CLIA minimal requirements, but may also initiate more stringent requirements.

State surveying agencies may impose additional requirements on CLIA labs, including personnel requirements, by adopting their own facility certification or licensing standards. Additionally, states that have standards and regulatory procedures deemed at least equivalent to CLIA requirements may apply to be exempt from CLIA processes and run their own laboratory regulatory programs. Currently, New York and Washington are CLIA exempt.

**10. Eleven states regulate clinical laboratory personnel, 39 states and the District of Columbia do not regulate clinical laboratory personnel (See Appendix):** Most of regulating states regulate both laboratory scientists and laboratory technicians, and grant licenses to generalists and limited licenses to specialists. Generally, scientists are able to perform any test in their specialty areas, and technicians are limited to performing tests that do not require independent judgment and work under supervision. Several states regulate CLIA-defined roles specifically, as well as testing personnel-- particularly the laboratory director, but also technical consultants/supervisors. Most states exempt CLIA-defined waived tests, however, Nevada creates its own list of exempt tests.

**11. From 2005 to 2010, CMS cited 37 Virginia labs for deficiencies directly related to insufficient numbers of testing personnel for the volume and complexity of tests performed, four of which involved immediate jeopardy citations:** The particular deficiency cited may include administrative/recordkeeping problems as well as actual deficiencies of testing personnel, so it is unclear if unqualified persons were performing tests in all cases. At least one complaint investigation revealed that unqualified staff performed tests, while another revealed that a person who failed proficiency tests performed tests without supervision. Laboratory directors and technical supervisors were also cited, as it is their responsibility to ensure that enough qualified staff is available, that they are competent, that they enroll in PT and that tests and quality control is performed properly. No evidence of harm directly linked to inadequately qualified personnel was found.

<sup>1</sup> See Judith Yost's presentation to CLIAC at its February 2010 meeting, Addendum C: <http://wwwn.cdc.gov/cliac/cliac0210.aspx>, and the September 2006 meeting, Addendum E: <http://wwwn.cdc.gov/cliac/cliac0906.aspx>.

**12. Staff received comment from clinical laboratory personnel, their professional organizations and the American Society of Clinical Pathologists supporting regulation. No patients, providers, facilities or other consumers of laboratory services provided comment supporting regulation. The Virginia Hospital and Healthcare Association provided comment opposing regulation.**

**13. The Regulatory Research Committee has previously recommended regulation of clinical laboratory personnel:** From the minutes of the Sept. 29, 2010 Regulatory Research Committee meeting: “On properly seconded motion by Mr. Boehm, the Committee recommended that regulation of medical laboratory scientists and technicians was warranted. They further recommended continuance of the study to enable them to determine the appropriate form of regulation and under which agency or board that regulation should be overseen.”

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## POLICY OPTIONS

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Several policy options are presented here with a bullet point list outlining the rationale for each. Waived tests and waived laboratories are exempt in all options.

**1. No professional regulation, with recommendation to license or certify laboratory facilities:** The committee examined the need to regulate laboratory personnel as a regulated health profession, and the licensure provisions in H.B. 601 in particular. We did not, however, look into regulation of clinical laboratories or clinical testing in general. However, if the Committee believes that CLIA regulations are not sufficient to ensure quality in clinical laboratories, the committee may recommend facility regulation as an alternative to professional regulation. The Office of Licensure and Certification (OLC) of the Virginia Department of Health licenses, regulates and inspects healthcare facilities and the Virginia Board of Health provides oversight and regulatory guidance in this area.

- Evidence of harm related to substandard regulation of testing personnel was not found.
- Clinical laboratories and laboratory personnel are already regulated through CLIA. CLIA has improved lab quality and proficiency test pass rates of non-waived labs.
- Deficiencies related to personnel were cited, indicating that CLIA enforces personnel standards.
- The Board’s criteria for regulating a new profession require that there be no alternatives to professional regulation that adequately protect the public, including strengthening existing consumer protection laws and regulations.
- While states must meet CLIA requirements, they may set additional requirements above CLIA’s requirements.
- If Virginia’s laboratories require additional regulation, regulating laboratory facilities provides an avenue of regulation that does not create an additional regulatory structure. VDH already surveys laboratories under CLIA.
- About 7.2 percent of Virginia’s CLIA registered labs are accredited and surveyed by private “deemed” organizations. Laboratory regulation would provide additional state oversight of these laboratories.
- Facility regulation may provide more flexibility in addressing quality issues, including raising personnel standards.
- Most errors occur in the pre- and post-analytical phases of the testing process, related to communication, data and specimen management and other administrative processes. Regulation of workers may pull resources from investments that may have a greater impact on lab and testing quality.
- Proficiency testing and laboratory inspections may provide a better means of ensuring quality, since outputs may be measured objectively and laboratory personnel do not provide direct patient care.
- Consumers of laboratory services are not seeking additional regulation of clinical laboratory personnel.

**2: Voluntary certification for testing personnel:** Creates title protection for laboratory scientists and laboratory technicians certified by national certification organizations. This would prevent uncertified persons



from referring to themselves as clinical/medical laboratory scientists and technologists or clinical/medical technicians or other protected titles. Voluntary certification is generally intended for practitioners specifically selected by the patient. It provides information to patients so they may better select their own practitioners without limiting the diversity of available practitioners. Voluntary certification for some personnel could be combined with licensure at higher levels (See “Policy Options in Combination,” pg.11).

- Laboratory personnel generally do not interact with patients in a manner that allows them to choose the personnel performing tests. Additionally, many of the point of care tests are waived tests. However, many non-waived laboratories are in physician’s offices, pharmacies and ambulatory health clinics. A few are associated with mobile labs, HMOs, home health agencies and other community-based health providers. Patients who use these services may benefit from official information on the qualifications of persons providing the tests in community-based laboratories.

**3. Licensure for management personnel:** Requires lab directors and/or technical supervisors to obtain a license as a laboratory director and/or technical supervisor. This usually includes an additional license for physician directors and supervisors.

- There is an inherent risk of harm related to laboratory testing that justifies regulation.
- Evidence of harm related to substandard performance of testing personnel was not found.
- Through CLIA, management is responsible for ensuring proper staffing. Citations for inadequate staffing are directed towards technical supervisors and laboratory personnel.
- CLIA only requires bachelor’s training with two years’ experience to fill the role of the lab director and the technical supervisor. Certification or membership in a professional group is not required.
- Regulation would add professional standards and ethics to lab management practice.
- Management is responsible for ensuring quality and best practices throughout the lab. Regulation of management would affect the quality of the pre- and post- analytical phases as well as the analytical phase.
- Continuing education would ensure lab directors and technical supervisors are up to date on technology, equipment and best practices in the laboratory sciences, including physician directors and supervisors.
- Through discipline, licensure of management personnel ensures that incompetent or unethical persons cannot operate or manage laboratories despite meeting minimal qualifications (i.e., it ensures those who are in charge of ensuring the competence of lab personnel meet laboratory competency standards themselves, cannot lab-hop, or open fly-by-night operations).

**4. Licensure for laboratory scientists:** Requires non-physicians performing tests that require independent judgment and responsibility, and non-physician technical supervisors and laboratory directors, to obtain a license.

- There is an inherent risk of harm related to laboratory testing that justifies regulation.
- The Board’s criteria for regulating a new profession at the licensure level require that practice be independent with a high degree of autonomy and little or no direct supervision. Laboratory scientists perform tests that require independent judgment and responsibility and thus may meet this criterion.
- Laboratory technicians do not perform tests that require independent judgment or responsibility. They are supervised by laboratory scientists, and thus may not meet the requirement for licensure.
- Licensure would add professional standards and ethics to persons performing the most complex tests, developing and interpreting tests and to persons supervising laboratory technicians and other laboratory personnel.
- Licensure for laboratory scientists ensures that non-physician laboratory management personnel are also licensed. Physician directors and supervisors would maintain standards under their physician license.



**5. Licensure for all testing personnel:** Requires licensure for laboratory technicians as well as laboratory scientists.

- There is an inherent risk of harm related to laboratory testing that justifies regulation.
- Although laboratory technicians do not perform tests that require independent judgment or responsibility, they perform tests of moderate to high complexity that can pose a risk of harm to patients.
- CLIA allows those with high school and on-the job training to perform these tests. Licensure as a laboratory technician would require formal certification and a post-secondary certificate or associate degree.
- Licensure for testing personnel ensures that non-physician laboratory management personnel are licensed as well.

## POLICY OPTIONS IN COMBINATION

The previous policy options may be used alone or in combination. The following chart provides an overview of all the options available.

Professional Level	Laboratory Management	Laboratory Scientist	Laboratory Technician	Rationale
<b>Option 1</b>	Not Regulated	Not Regulated	Not Regulated	• See Option 1
<b>Option 2</b>	Not regulated	Voluntary Certification	Voluntary Certification	<ul style="list-style-type: none"> <li>• CLIA is effectively regulating laboratories</li> <li>• Patients at community-based labs may benefit from information on the qualifications of laboratory personnel</li> </ul>
<b>Option 2a</b>	Not regulated	Voluntary Certification	Not regulated	<ul style="list-style-type: none"> <li>• CLIA is effectively regulating laboratories</li> <li>• Patients at community-based labs may benefit from information on the qualifications of those supervising lab personnel</li> </ul>
<b>Option 2b</b>	Licensure	Voluntary Certification	Not Regulated	<ul style="list-style-type: none"> <li>• The Board determines management requires licensure</li> <li>• Patients at community-based labs may benefit from information on the qualifications of those supervising lab personnel</li> </ul>
<b>Option 2c</b>	Licensure	Voluntary Certification	Voluntary Certification	<ul style="list-style-type: none"> <li>• The Board determines management requires licensure</li> <li>• Patients at community-based labs may benefit from information on the qualifications of laboratory personnel</li> </ul>
<b>Option 2d</b>	Licensure	Licensure	Voluntary Certification	<ul style="list-style-type: none"> <li>• The Board determines management and laboratory scientists require licensure.</li> <li>• Patients at community-based labs may benefit from information on the qualifications of laboratory personnel.</li> </ul>
<b>Option 3</b>	Licensure	Not Regulated	Not Regulated	• See Option 3
<b>Option 4</b>	Not regulated	Licensure	Not regulated	• See Option 4
<b>Option 4a</b>	Licensure	Licensure	Not regulated	<ul style="list-style-type: none"> <li>• Option 4 and</li> <li>• All those using independent judgment and providing supervision of laboratory workers require licensure</li> <li>• Laboratory management, including physicians, require licensure specific to their management role beyond that of laboratory scientists</li> </ul>
<b>Option 5</b>	Not regulated	Licensure	Licensure	• See Option 5
<b>Option 5a</b>	Licensure	Licensure	Licensure	<ul style="list-style-type: none"> <li>• Option 5 and</li> <li>• All those performing non-waived tests require licensure</li> <li>• Laboratory management, including physicians, require licensure specific to their management role beyond that of laboratory scientists</li> </ul>

## APPENDIX: STATE LICENSURE REQUIREMENTS

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**California:** California's Laboratory Field Services, a division of the Department of Public Health, licenses both laboratory facilities and laboratory personnel. California licenses Clinical Laboratory Scientists, Cytotechnologists, Medical Laboratory Technicians, Laboratory Directors and Phlebotomists. Clinical Laboratory Scientists may seek licensure as generalists, or in one of eight specialty areas. Laboratory directors are licensed in one of seven specialty areas.

**Florida:** Laboratory Scientists, Laboratory Technicians, Laboratory Directors and Laboratory Supervisors are licensed in one of 14 specialty areas. All licensed personnel are able to collect, process, store and ship specimens and perform tests within their specialty area. Laboratory scientists, supervisors and directors may interpret test results.

**Georgia:** Until July 2010, Georgia facility licensure requirements had additional personnel requirements. Testing personnel had to have a national certification as a Laboratory Scientist or Laboratory Technician. In 2010, Georgia repealed its clinical laboratory licensure law, reverting to CLIA standards.

**Hawaii:** Hawaii licenses Laboratory Directors, Clinical Laboratory Specialists, Cytotechnologists, Medical Technologists (Laboratory Scientists) and Medical Laboratory Technicians (Laboratory Technicians). Medical Technologists are Bachelor trained Laboratory Scientists; Clinical Laboratory Specialists are Bachelor trained Scientists in one of six specialties.

**Louisiana:** Louisiana licenses Clinical Laboratory Scientists: Generalist, Clinical Laboratory Scientist: Technician, Clinical Laboratory Scientist: Specialist, Cytotechnologists and Laboratory Assistants. Phlebotomists must be certified if they are not employed or supervised by a physician, clinic, or other licensed health care facility. Clinical Laboratory Generalists may perform all tests. Clinical Laboratory Specialists may perform all tests within a specialty area. Clinical Laboratory Technicians may only perform tests that do not require "independent judgment or responsibility" and may only perform high complexity tests under supervision. Laboratory assistants may only perform tests that do not require "independent judgment or responsibility" under supervision of a licensed health care provider or laboratory director, or may perform high complexity tests under supervision as required in CLIA.

**Montana:** Montana licenses Clinical Laboratory Scientists, Clinical Laboratory Specialists and Clinical Laboratory Technicians. Scientists may perform all tests. Specialists may perform all tests within a specialty area, and Technicians may perform tests that require limited independent judgment and are performed under the supervision of a laboratory scientist, supervisor or director.

**Nevada:** Nevada licenses lab directors, general supervisors, clinical laboratory technologists (scientists), medical technicians, and laboratory assistants. Nevada also licenses both technologists (scientists) and technicians in several specialties. The general supervisor has a role similar to the technical supervisor/consultant. Technologists may perform all tests, while technicians are limited to waived or moderate complexity tests, or high complexity tests which have results read from an instrument and do not require interpretation or intervention by the operator during the analytical phase. Laboratory Assistants may assist with tests under direct supervision with specific exceptions.

**New York:** New York licenses Clinical Laboratory Technologists (scientists), Certified Clinical Laboratory Technicians, Cytotechnologists and Certified Histological Technicians. Technologists may pursue a full license, or a restricted license that limits practice to one of six specialty areas. Technologists may perform all tests pursuant to a full license or limited specialty area. Technicians may only perform tests that require limited judgment.

**North Dakota:** North Dakota licenses Laboratory Scientists, Laboratory Technicians and Specialists.

**Rhode Island:** Rhode Island regulates Clinical Laboratory Scientists, Clinical Laboratory Technicians, Cytotechnologists, Histologic Technicians and MOHS (micrographic surgery) Technicians. Laboratory scientists may be licensed as generalists, or in one of eight specialties. Scientists may perform all tests within their license area. Technicians may perform tests which do not require independent judgment under supervision of a laboratory scientist, supervisor or director.

**Tennessee:** Tennessee licenses Laboratory Directors, Supervisors, Technologists (scientist), Technicians and special analysts. Laboratory supervisors fulfill roles similar to the technical supervisor role; technologists may perform any test laboratory. Special analysts may perform tests within a specific specialty. Technicians may only perform tests which require limited skill, responsibility or independent judgment under the supervision of a technologist, supervisor or director.

**West Virginia:** West Virginia requires licenses for laboratory directors, consultants, scientists, and technicians and point of care technicians in eleven specialties based on positions and functions held in a laboratory. Scientists perform all tests within approved specialty areas, while technicians may only perform tests requiring limited exercise of independent judgment under supervision of a laboratory director or supervisor. Point of Care Technicians may only perform point of care tests of moderate complexity when reporting directly to a physician and under the supervision of a laboratory director and supervisor. The consultants and directors fulfill roles equivalent to those in CLIA, and must meet the same requirements.